RISK: Health, Safety & Environment (1990-2002)

Volume 10 | Number 4 Article 3

September 1999

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Introduction

The 104th Congress enacted significant changes to two statutes that affect the use of pesticides: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA governs U.S. registration, sale and use of pesticide products. The FFDCA establishes standards under which the U.S. Environmental Protection Agency (EPA) sets pesticide residue levels (tolerances) in food and animal feed. The vehicle for these changes was the Food Quality Protection Act (FQPA) of 1996[1] that established a new food safety standard. It requires a "reasonable certainty of no harm" from any legally permissible pesticide residue, while recognizing the benefits of pesticide use on food crops. Since the FQPA was enacted, EPA implementation of the new standard has been carefully observed and often criticized by farmers, chemical manufacturers, environmentalists, other stakeholders and the Administration. This article evaluates the status of the FQPA implementation and related issues; particularly its potential effects on certain popular pesticides used in food production and processing.

Food Quality Protection Act Mandates

A key purpose of the FQPA was to coordinate pesticide registration under the FIFRA with FFDCA tolerances to ensure that any pesticide used on food would leave only a "safe" residue. The FFDCA, as amended, defines "safe" to mean that EPA "has determined that there

* The views expressed here are the author's and do not necessarily represent those of the Congressional Research Service.

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1 Pub. L. 104-170.

is a reasonable certainty that no harm will result from aggregate exposure... including all anticipated dietary exposures and all other exposures for which there is reliable information."[2]

To ensure the safety of pesticide tolerances established prior to August 1996, EPA must reevaluate the tolerances against the new safety standard. The Act requires reevaluation of 33% of existing residue limits for food-use pesticides by August 1999, 66% by August 2002 and 100% by August 2006. It also directs EPA to reevaluate the riskiest pesticides first.

If EPA finds that food pesticide residues may pose a risk greater than allowed under the FQPA, the FFDCA tolerance level and the FIFRA registration (that is, product labels) to restrict the number or manner of approved pesticide uses, must be changed to reduce human exposure to a "safe" level. In assessing a pesticide residue tolerance, the FQPA requires EPA to consider:

- the susceptibility of children to exposure and/or to adverse health effects;
- potential disruptive effects on endocrine systems;
- potential effects of in utero exposure;
- cumulative risk from all sources and through all routes of exposure; and
- aggregate risks due to exposure to the pesticide and to other pesticides that may have similar toxic effects (i.e., a "common mechanism of toxicity").

FQPA Implementation

Generally, EPA is on schedule. It expects to reach or surpass the August 1999 milestone for reevaluating and, if necessary, modifying 33% of tolerances for pesticide residue levels in food to ensure the safety of children and other consumers. EPA continues to work with stakeholders to implement the new law. Pesticide producers and users are working to secure assurances that the risks of popular organophosphates and other pesticides will be fairly evaluated by EPA, based on real data, not worst-case assumptions. At the same time, environmental and consumer groups are trying to ensure prompt regulation of pesticides that are not "safe." The FQPA implementation is complicated by several particularly contentious issues.

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2 FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. 346a(b)(2)(A)(ii) (1999).

Progress Towards Milestones

On the date of the FQPA enactment, there were 9,728 residue tolerance levels and exemptions, in effect for active and inert pesticide ingredients. EPA divided these into groups based largely on relative risk to public health, and published a schedule for reevaluation of tolerances.[3] The first group of pesticides subject to tolerance reassessment includes:

- organophosphates, carbamates, and organochlorines;
- probable and some possible human carcinogens;
- high-hazard inert ingredients;
- pesticides that exceed their reference dose — RfD, an estimate of a safe daily exposure levels likely to be safe over a lifetime;
- pesticides subject to reregistration requirements[4] and for which EPA would be issuing Reregistration Eligibility Decisions after the FQPA enactment; and
- pesticides whose tolerances and exemptions are in the process of being revoked.

An itemized list of pesticides and request for public comments appears with the schedule.[5] EPA expected to complete reevaluation of more than 3,000 tolerances before the August 1999 deadline. In FY1998, it reevaluated more than 1,400 tolerances and revoked 874, according to a fact sheet.[6] About 415 tolerances were evaluated in FY1997.

Stakeholder Involvement

According to EPA, pesticide regulations directly affect approximately 30 major pesticide producers, 100 smaller producers, 2,500 formulators, 29,000 distributors and retailers, 40,000 commercial pest control firms, 1 million farms, 3.5 million farm workers, several million industry and government users, and all households.[7] Within each of these groups, distinct subgroups have different views on the federal role in pesticide regulation. Some politically active stakeholder

3 62 F. R. 42019 (1997).

4 EPA has a deadline of 2002 for completing the reregistration of pesticides registered prior to 1984. Amendments to the FIFRA in 1972 directed the EPA to "reregister" approximately 35,000 older products, thereby, assessing their safety in light of current standards.

5 *Supra* note 3.

6 EPA, Pesticide Program Highlights from Fiscal Year 1998 (1998).

7 EPA, Office of Prevention, Pesticides and Toxic Substances, 1996 Food Quality Protection Act Implementation Plan, Mar. 1997, at 4.

groups include multinational pesticide producers (i.e., Monsanto), specialty chemical manufacturers, agribusinesses, organic farmers, dairy farmers, fruit and nut growers, landscape gardeners, environmentalists, and consumer groups.

A handful of contentious issues has potentially far-reaching impacts on the availability of pesticides for particular uses, the cost of food and other consumer products, and international competitiveness of U.S. agricultural products. EPA is seeking to resolve these issues through cooperative decisions involving the major stakeholders. Theses issues are summarized below.

EPA has been working with several committees since the law's enactment to ensure an open decision-making process. A Food Safety Advisory Committee (FSAC), consisting of growers, pesticide companies, environmental groups, and state officials, was established immediately after the FQPA passage and they developed interim decision policies, which still are being employed. This committee finished its work in December 1996. A permanent, broadly representative advisory committee, the Pesticide Program Dialogue Committee, has had ongoing discussions about the FQPA implementation. EPA has also involved its FIFRA Science Advisory Panel of independent scientists in developing approaches for implementing several of the more technically challenging FQPA provisions. Another standing committee advising EPA is the State FIFRA Research and Evaluation Group. Several task forces and ad hoc working groups have worked on specific issues. For example, EPA created a task force to identify data and methods needed to apply the 10-times safety factor to protect the health of children.[8]

Despite these consultative efforts, growers and chemical manufacturers continued to express concerns, and Vice President Gore sent a memorandum on April 8, 1998 to EPA directing the Agency to work more closely with the U.S. Department of Agriculture and the stakeholders in implementing the FQPA.[9] In response, EPA established a new advisory group and committed itself to apply sound

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8 Regarding the EPA implementation process and advisory committees, *see generally* <http://www.epa.gov/oppfead1> and <www.epa.gov/pesticides>.

9 *See* EPA Tolerance Reassessment Advisory Committee, Meeting Summary, May 28, 1998 at <http://www.epa.gov/oppfead1/trac/summary1.htm>.

science, employ an open process of decision making, and ease any necessary transition to new rules to not jeopardize the agriculture and farm communities. The Tolerance Reassessment Advisory Committee (TRAC) was established jointly by EPA and USDA as a subcommittee of EPA's National Advisory Council for Environmental Policy and Technology.[10] The 45 members represent environmental and public interest groups; pesticide industry and trade associations; users, growers, and commodity organizations; pediatric and public health organizations; federal agencies, tribal, state, and local governments; academia and consumers. However, the Environmental Working Group resigned claiming that the Clinton Administration had failed to take action to protect children from pesticide risks.

Implementation Issues

The TRAC has identified nine science policy issue areas affecting implementation of the FQPA with regard to tolerances:[11]

- applying the FQPA 10-fold safety factor for children;
- dietary exposure assessment (the role of Monte Carlo [probability] methods and the percentile of food consumption included);
- exposure assessment (how to interpret a result of "no detectable residue");
- dietary exposure estimates (need for better data);
- dietary (drinking water) exposure estimates;
- assessing residential exposure;
- aggregating all non-occupational exposures;
- cumulative risk assessments for pesticides with a common mechanism of toxicity (e.g., organophosphates); and
- appropriate toxicity endpoints for risk assessments of organophosphates.

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10 *See* <http://www.epa.gov/pesticides/trac> for an overview of TRAC.

11 63 F. R. 58038 (1998). Arguments surrounding statistical issues are technical but the impact may be substantial. For example, EPA currently uses a 99.9th percentile to generate risk estimates. According to a summary of a meeting, the FIFRA Scientific Advisory Panel "differed on whether setting criteria at the 99.9th percentile is a conservative approach. However, if the 99.9th percentile is utilized... 23,000 children[] will still be exposed to acute effects" (<http://www.epa.gov/pesticides/SAP>). Some want EPA to use a 95th percentile, which would leave a greater percentage of the population exposed to potential acute effects but would allow the pesticide to be used more.

EPA is developing policy guidance documents on each of these issues.[12] Draft policies are getting published in the Federal Register and, although it is under no obligation to do so, public comments are welcomed. EPA will evaluate the policies after considering public comments. The remaining two TRAC meetings will consider means of reducing adverse impacts of any new pesticide regulations on growers and others who use those pesticides.

A particularly contentious implementation issue revolves around the FQPA directives to use "available data" and "reliable data," as well as the FQPA mandate to order testing if EPA determines that the data are "reasonably required to support the continuation of a tolerance or exemption that is in effect . . . for a pesticide chemical residue on a food."[13] Stakeholders disagree regarding an appropriate course of action for EPA to pursue when there is insufficient "reliable" data to estimate risk. Pesticide producers ideally would like EPA to delay estimating risk until reliable data can be collected; environmentalists would like EPA to estimate risk based on "available" data and, if unacceptable risk is found, to reduce the potential for human exposure through regulations. Alternatively, EPA may impose a time-limited temporary tolerance for pesticide residues on certain crops (a procedure allowed by FQPA and in current use for emergency exemptions).[14] This may prove to be an acceptable compromise between environmental groups and pesticide producers.

Members of the pesticide industry also want EPA to "call in" data, particularly on exposure levels. Although it is the pesticide producers who conduct toxicity testing without needing to wait for an EPA order to produce the data, such an order provides certain legal and financial protections, and probably would delay revocation of a tolerance pending data development.

Food Tolerances for Organophosphate Pesticide Residues

Organic phosphates, or organophosphates, are complex synthetic compounds. Two well-known organophosphates are methyl parathion and malathion. In agriculture, organophosphates are used as broadly

12 *Id.*

13 FFDCA § 408(f)(1), 21 U.S.C. § 346a(f)(1) (1999).

14 *Id.* § 408(b)(2)(B), 21 U.S.C. § 346a(b)(2)(B) (1999).

effective insecticides; for example, to kill boll weevils, spider mites, fruit flies, or aphids. Various organophosphates are used on fruit trees, vegetables, ornamental plants, cotton, corn, soybeans, rice, and wheat.

EPA determined that organophosphates are among the pesticides posing the greatest risks to human health and the environment, and, therefore, the safety of these products must be evaluated during the first three-year period following enactment of the FQPA in 1996.[15] Organophosphates have a highly variable, toxic effect on the nervous systems of people and other animals. Some are highly acutely toxic, others much less so; but, because they share a common mechanism for exerting this effect, they are the first pesticides that EPA is considering as a group.[16] There are 1,800 tolerances established for various organophosphate pesticide residues on crops.

Growers and pesticide manufacturers are concerned about the impact of the FQPA implementation on these widely used pesticides. Although rumors that EPA might cancel registrations for the entire class of organophosphates seem to be alarmist, concern about the future availability of some of these pesticides for certain uses is justified because evidence suggests that cumulative risk probably is greater than allowed under the new law. EPA conducted preliminary risk assessments for 28 organophosphates and made the results available for public comment.[17] These assessments indicate that the risks of some individual organophosphates (e.g., methyl parathion) exceed acceptable levels, even if non-food sources of exposure to the pesticide are not considered. However, most of the preliminary risk assessments relied on numerous assumptions about exposure, because the data were either unavailable or unreliable. EPA is currently collecting data on rates of use of the organophosphates on various commodities. As more data are collected, assessments might narrow the range of probable exposures and risks to levels that are reasonably certain to be safe, as farm groups and pesticide producers contend. On the other hand, the data might support conclusions of the Environmental Working Group, a consumer safety advocacy group, which claims that children are exposed to unsafe

15 62 F.R. 42019 (1997).

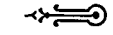
16 Organophosphates inhibit cholinesterase, an enzyme necessary for the proper functioning of the nervous system.

17 Risk assessments can be downloaded from <http://www.epa.gov/oppsrrd1/op/>.

levels of organophosphates on pears, apples, grapes, and peaches, and that the exposure can damage developing brains and nervous systems.[18]

Conclusion

When Congress passed the FQPA by unanimous votes in both Chambers, many hailed it as one of two "risk-based" laws enacted in 1996. It established a new standard for food safety that recognized the benefits of pesticide use on food crops, but also guaranteed that there would be a reasonable certainty of safety from pesticide residues. Two and one-half years after its enactment, EPA appears to be making progress at an acceptable rate relative to statutory deadlines. However, it is not clear whether the promise of the FQPA will be fully realized, since contentious implementation issues remain unresolved.



[18] Richard Wiles et al., How 'Bout Them Apples? Pesticides in Children's Food Ten Years after Alar, (Environmental Working Group 1999).